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November 30, 1999

VIA UPS NEXT DAY AIR

Dr. Elizabeth Yetley

Office of Special Nutritionals (HFS-450)

Food and Drug Administration

200 C Street, S.W.

Washington, D.C. 20204



***Re: Fulfillment of Reporting Obligation
Under 21 U.S.C. § 343(r) and 21 CFR § 101.93***

Dear Dr. Yetley:

Pure Encapsulations, Inc.,¹ by counsel and in accordance with 21 U.S.C. § 343(r) and 21 CFR § 101.93, hereby submits an original and two copies of its notification within thirty days of first marketing its products with the statements presented below. Pure Encapsulations retains scientific documentation supporting the statements.

1. **Supplement Brand Name**

Calcium-d-glucarate

Text of Statements of Nutritional Support

Supports healthy cell structure and function.

Developed by researchers at M.D. Anderson Cancer Center and currently in trials at the National Cancer Institute and AMC Cancer Center, calcium-d-glucarate, a patented nutraceutical, is a powerful nutrient derived from fruits and vegetables.

Calcium-d-glucarate has been shown to help target beta-glucuronidase enzyme activity supporting the process by which healthy cells eliminate waste and foreign elements.

Calcium-d-glucarate helps to maintain healthy cell structure and function.

¹ The address for Pure Encapsulations is 490 Boston Post Road, Sudbury, Massachusetts 01776.

LT 4700

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2. **Supplement Brand Name**

Inositol hexaphosphate (IP6)

Text of Statements of Nutritional Support

Cellular and natural defense system support.

In studies IP6 promotes healthy cell metabolism and maintains proper enzyme activity in cells.

The unique conformation of IP6 gives it the specific ability to modulate hydroxyl radical formation, supporting natural defense mechanisms.

IP6 provides highly-charged antioxidant and cellular function support shown to nutritionally promote prostate, breast, colon, and liver cell health.

3. **Supplement Brand Name**

Ginkgo 32/9 80 mg

Text of Statements of Nutritional Support

Superior potency ginkgo extract

The Ginkgo 32/9 80 mg extract offers enhanced Ginkgo biloba support, providing 32% ginkgoheterosides and 9% terpene lactones per capsule.

4. **Supplement Brand Name**

ProstaFlo

Text of Statements of Nutritional Support

Flower pollen extract for prostate and urinary function.

Powerful prostate support components can be derived from both fractions of the flower pollen extract, consisting of alpha amino acids and phytosterols, respectively.

The benefits of flower pollen extract have been demonstrated in a large number of double-blind and long-term clinical trials, including one study that showed prostate health was supported in 85% of individuals.

Fat soluble constituents have been shown to promote proper leukotriene and prostaglandin production, maintaining healthy prostate tissue and urinary flow.

Together, both extracts, alpha amino acids and phytosterols, syngeristically support normal urethral smooth muscle relaxation, enhancing healthy urinary function.


Compounds of the water soluble fraction encourage healthy prostate cell metabolism by modulating dihydrotestosterone (DHT) activity.

Flower extract provides a healthful spectrum of nutrients, including vitamins, minerals, carotenoids, falvonoids, nucleic acids, and enzymes for optimal synergy.

ProstaFlo contains a highly-concentrated, 20:1 combination of water and fat soluble flower pollen extracts from the Graminaceae family, and a broad spectrum of important nutritional constituents for prostate health and urinary function support.

In accordance with 21 USC § 343(r)(6) and 21 CFR § 101.93(c), each of the above statements will be followed by an asterisk that will be cross-referenced to another asterisk on the very same panel or page next to which the following statement will appear in a box in bold face type: **"These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."**

Respectfully submitted,



Jonathan W. Emord
Claudia A. Lewis-Eng
Steven W. Allis

Attachment

Certification

I, Ray Hamel, General Manager of Pure Encapsulations, Inc., hereby certify that the information contained in the foregoing notice is complete and accurate and that Pure Encapsulations has substantiation that the statements are truthful and not misleading.

Executed on: 11/30/99

Ray Hamel
Ray Hamel